Hearing on

Clinical Laboratory Quality: Oversight Weaknesses Undermine Federal Standards

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Testimony by

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I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. We appreciate the opportunity to present testimony on the subject of today's hearing, "Clinical Laboratory Quality: Oversight Weaknesses Undermine Federal Standards."

I would first like to thank the Subcommittee on Criminal Justice, Drug Policy, and Human Resources for taking a leadership role in urging improvements in laboratory services in this country in the wake of the highly-publicized laboratory testing problems that were identified in the Baltimore region. The problems found at Maryland General Hospital's laboratory underscore the importance we all should place on fostering cultures of safety within health care organizations that encourage voluntary reporting of staff concerns to organization leaders, and ultimately to responsible quality oversight bodies. Absent such cultures, critical information may go unreported or surface too late to avoid harm to patients.

The Joint Commission would also like to congratulate the Government Accountability Office (GAO) for its efforts to study the quality of testing in our nation's clinical laboratories; the effectiveness of quality oversight body assessment of laboratory performance; and the Medicare program's oversight of the implementation and appropriate application of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

Background

Founded in 1951, the Joint Commission is a private, not-for-profit entity dedicated to improving the safety and quality of health care. Its member organizations are the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians; and the American Dental Association. In addition to representation from these organizations, the 29-member Board of Commissioners includes an at-large nursing representative and six public members whose expertise spans such diverse areas as ethics, public policy, insurance, academia, and patient advocacy.

The Joint Commission currently accredits approximately 15,000 health care organizations in the United States. These include hospitals (both general acute care and specialty), critical access hospitals, clinical laboratories, ambulatory care organizations, office-based surgery providers, assisted living facilities, behavioral health care programs, home care agencies, hospices, home medical equipment suppliers, and long term care organizations.

Among the Joint Commission accredited entities are more than 3,000 laboratories that hold CLIA certificates of various types; these include independent laboratories and those that are integral to other health care organizations, such as hospitals. Laboratory surveys are conducted by experienced medical technologists and pathologists who have passed Joint Commission's rigorous certification examination. The Joint Commission surveyors are distinguished from other accrediting body surveyors in that they are not volunteers, but rather are dedicated employees who have extensive knowledge of the full range of laboratory services that are provided in a variety of settings, and are required to participate in ongoing training exercises.

Ensuring that its accredited laboratories are providing high quality and safe services is one of the Joint Commission's highest priorities. Many clinical diagnoses and most patient clinical management are based on the results of laboratory tests, yet attention to the level of quality in hospital laboratories is often eclipsed by other quality concerns within the larger organization. Recognizing the critical

importance of laboratory services, the Joint Commission has designated the laboratory as an "essential" hospital service. This designation has elevated the importance of the laboratory's compliance status in determining the overall accreditation status of a hospital. This policy underscores the patient care implications of laboratory quality, and the need for hospital leaders to pay particular attention to laboratory processes and outcomes.

Keeping Patients Safe

Joint Commission efforts to improve patient safety in all types of health care organizations are based upon a fundamental recognition of the need for organization leaders and health care practitioners to adopt a "systems approach" to managing risk and keeping inevitable human error from reaching patients. The systems approach idea is borrowed from both the field of engineering and from quality control principles which have been successfully applied in manufacturing and other industries to mitigate the effects of human error. This approach to safety—"systems thinking"—requires the application of tools such as retrospective root cause(s) analysis when adverse events occur. It also requires prospective failure mode and effects analyses to identify and eliminate risks in identified vulnerable processes before actual adverse events can occur. Improving systems within laboratories requires attention to the entire testing process—starting with proper sample preparation and continuing with the appropriate selection of tests, application of proper analytics, correct and understandable portrayal of results, and utilization and timely reporting of these results.

This approach also requires a "blame-free" environment in which errors and "near misses" are systematically identified, rather than hidden, so that they regularly become learning experiences for the organization and its staff. A safety-focused learning environment is one in which safety is always top of mind; in which the identification and reporting of errors and unsafe conditions is rewarded, not punished; in which a commitment to honesty, transparency and where appropriate apology and if necessary re-testing, characterize the relationship with patients who have been unintentionally harmed; and in which there is constant vigilance for emerging risks. This type of organizational environment only develops when the organization's managerial and clinical leaders work collaboratively and deliberatively to create it.

The Joint Commission's standards, survey process, and other quality and safety improvement initiatives are designed to stimulate and facilitate the creation of cultures of safety within accredited organizations.

Specific Joint Commission Efforts to Improve Quality in Laboratories

With the fore noted framework in mind, the Joint Commission has created a substantial portfolio of initiatives, practical tools, and solutions to further enhance the value and reliability of accreditation. These efforts include:

- The recent transition to unannounced surveys which underscores that the laboratories be in continuous compliance with all accreditation standards.
- The expanded use of data to focus and drive the onsite assessment.
- Continuing attention to reduce the risk of adverse events.
- The tracing of patients and their specimens through the continuum of laboratory services during the unannounced survey to determine compliance with each applicable standards.

- Ready public access to a robust complaint process, availability of a toll-free complaint hotline, confidentiality for those who report concerns about an accredited organization, and use of compliant data in the onsite evaluation process.
- The use of an annual self-assessment tool and process to identify continuing opportunities for improvement and support continuous standards compliance.

The Joint Commission also works closely with accredited laboratories that have been cited for standards deficiencies by requiring specific corrective actions and monitoring these laboratories to ensure that substandard patterns of performance are actually remedied and do not recur. Combining this rigorous evaluation and monitoring approach with the educational dimension of the Joint Commission's accreditation process is critical in the ongoing efforts to achieve lasting improvement in laboratory performance. Simply pointing out deficiencies in laboratory performance does not automatically translate to effective resolution of those identified problems.

Partnerships to Enhance Laboratory Quality

The Joint Commission believes that its close working relationship with the Centers for Medicare & Medicaid Services (CMS) on laboratory issues demonstrates the value of public-private partnerships in improving health care, and has served laboratories and Medicare beneficiaries well. The Joint Commission makes a special effort to work with state and federal agencies and other private accrediting bodies to assure effective oversight of laboratories and is committed to continuous efforts to improve communication and coordination among these parties. These efforts are critically important because a number of oversight bodies have roles in overseeing the quality of laboratory services. The responsible oversight bodies have forged relationships that make the system work to reduce unnecessary duplication, control costs, and leverage improvement when deficiencies are found to exist, but these relationships also create significant communication challenges. The Maryland General laboratory issues starkly illustrate the need to more tightly weave together the oversight fabric so that it identifies and addresses performance problems in a timely fashion. Because the focus of the oversight process must always be the patient, it is incumbent on each oversight body to share significant complaint information—
that it alone may receive—with all of its oversight partners in a timely manner, so that effective remedial action can be thoroughly leveraged.

The initial public/private sector partnership in the oversight of laboratories began when the Congress granted the Joint Commission deemed status for Medicare hospital requirements in 1965. Under this deeming provision, the Congress determined that Joint Commission hospital accreditation provides an assurance of compliance with the Medicare Conditions of Participation. One of the Medicare Conditions identifies laboratory services as a basic hospital function and required service. As part of its hospital accreditation program, the Joint Commission verifies that the hospital laboratory has a valid CLIA certificate and that the laboratory services are adequate to meet the needs of the hospital's patients.

Following enactment of the CLIA legislation, the Joint Commission was one of several accrediting bodies to receive recognition from CMS for approval of laboratories to receive CLIA Certificates of Accreditation. Under its laboratory program, the Joint Commission accredits laboratories in hospitals and other health care facilities as well as independent laboratories.

When a hospital (or any other) laboratory elects accreditation by the Joint Commission, a biennial laboratory surveys are conducted to determine compliance with the applicable CLIA Condition-level requirements. When a hospital elects to have its laboratory accredited by another CMS-approved accrediting body with which the Joint Commission has a partnership agreement, the Joint Commission relies upon the findings of its partner. In all cases where a hospital laboratory fails to demonstrate compliance with either the CLIA requirements (as determined by the Joint Commission or by another CMS-approved accrediting body) or the hospital Conditions of Participation for laboratory services, the hospital and the laboratory are both subject to the possible loss of their respective accreditation awards.

The Joint Commission maintains partnership agreements with other nationally-recognized accrediting organizations in order to reduce the cost and duplication of survey and inspection activity experienced by hospitals and other health care organizations. These specifically include partnerships with the College of American Pathologists (CAP) and COLA. Before becoming a Joint Commission partner, each organization must undergo extensive review of its standards and standards development process; survey process; selection, training and monitoring of surveyors; and accreditation decision process.

Following upon the intensive review of the Maryland General situation, the Joint Commission has negotiated an enhanced information-sharing mechanism with CAP to assure the exchange of important information. For example, CAP now provides the Joint Commission reports on CAP-accredited laboratories in Joint Commission-accredited hospitals for all laboratories that exceed a certain threshold of deficiencies. The Joint Commission then reviews this information and determines appropriate courses of action on a case-by-case basis. These actions may include special for-cause unannounced surveys and, where appropriate, a change in the hospital's accreditation status.

The Joint Commission also continues to enhance the communication of information it provides to the states regarding its accredited organizations. For example, to assist the states in fulfilling their licensure function, forty-five state hospital licensing agencies recognize the Joint Commission's hospital accreditation program as an element of the state's licensure process. The most common form of recognition involves the state's acceptance of a hospital's accreditation in lieu of the conduct of its own routine state licensure inspection. The Joint Commission pays specific attention to effective and timely sharing of information not only with state licensing bodies but also with CMS.

As part of another collaborative effort to improve the quality of laboratories, the Joint Commission, along with state agencies and other accrediting bodies, is involved in the CMS Partners in Laboratory Oversight project. The goal of this partnership is to encourage communication and coordination and promote more effective oversight of our nation's laboratories, and therefore drive continuous improvement in quality and patient safety in these laboratories.

Comments on the GAO Report

The Joint Commission welcomes the GAO report on the oversight of quality in laboratories. This report, *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*, calls on Congress to give CMS greater power to monitor the accreditation of laboratories. The Joint Commission supports the emphasis on achieving a balance between timely identification and resolution of performance issues in laboratories and the education and improvement of objectives inherent in the accreditation process. While the Joint Commission commends the GAO for its efforts, we would like to highlight several issues with respect to the GAO recommendations.

Standardizing Categorization and Survey Findings

The GAO recommendation that CMS standardize the categorization and reporting of survey findings, may theoretically have the potential to simplify the administrative oversight of the laboratory program, however it may also stifle innovation in the creation of patient safety evaluation approaches and thereby ultimately compromise the safety of patient care. This recommendation assumes that CLIA requirements and categorizations are a "gold standard" rather than a set of basic expectations for laboratories, and that more advanced performance standards do not exist. In fact, the rationale for relying on private sector accreditation is that it provides a level of flexibility in the timely setting of higher standards not readily available in a regulatory environment. When Congress established the accreditation option—with the caveat that the relevant standards "meet or exceed" federal regulations—it recognized that other approaches to quality improvement can be more innovative and effective in ensuring quality and patient safety, and that the private sector can be more nimble than the government in developing and applying state-of-the art performance expectations and assessment techniques. This GAO recommendation fails to recognize that the Joint Commission—like its colleague accrediting bodies—use different and more sophisticated approaches to assessing laboratory performance. Compliance with this recommendation would require a complete revamping of our laboratory process.

Notwithstanding the foregoing, the Joint Commission believes that CMS could and should play a lead role in developing a common, agreed-upon taxonomy that could be used by all laboratory oversight organizations to track serious deficiencies. As the GAO report notes, state survey agency determinations that Condition-level requirements are out of compliance are highly subjective and, by their nature, inconsistent. If all oversight organizations were to agree on criteria as to what constitutes a serious deficiency, this would create the desired comparability without requiring accrediting bodies to change their standards or the ways in which they categorize and document findings. We believe that this GAO recommendation to standardize the categorization and reporting of survey findings should be set aside in favor of direction to CMS to take the lead in coordinating a joint effort to develop common definitions of what constitutes serious deficiencies that should be reported to CMS.

Sanctions on Laboratories with Repeat Condition-level Deficiencies

The Joint Commission questions the GAO recommendation that CMS arbitrarily impose more frequent sanctions on laboratories with repeat Condition-level deficiencies. First of all, more information respecting such citations is essential because a variety of standards contribute to each Condition of Participation. Therefore, the "Condition" may be found to be out of compliance on two different occasions for very different reasons. Further, the laboratory may lack the expertise to fix the identified problem. Determining when to employ a punitive versus an educational or collaborative approach to promoting compliance is a difficult judgment and should not be an automatic determination.

The most appropriate way to manage reckless behavior is through sanctions or other disciplinary action. However, we contend that most laboratories with consecutive Condition-level deficiencies are actually exhibiting behavior that they mistakenly believe to be justified. Quality experts call this "at-risk" behavior to differentiate it from reckless disregard. The best way to manage at-risk behavior is to increase situational awareness, create incentives for healthy behaviors, and provide tools and solutions. Highly regarded patient safety studies overwhelmingly support the conclusion that punishment

encourages organizations to cover up problems. Thus, the Joint Commission believes that GAO's call for CMS to simply impose more sanctions on laboratories with repeat Condition-level deficiencies is likely to be counterproductive.

Validation Surveys

We also believe that GAO has misinterpreted its validation survey data. It concludes that "independent" surveys—more commonly referred to as "look-behind" surveys—are more effective than simultaneous surveys in identifying Condition-level deficiencies that were missed by accrediting organizations. However, the data presented in the report do not support this assertion. The Joint Commission found that in re-evaluating the same data, the proportion of Condition-level findings was generally equivalent in both types of surveys. We would like to emphasize that there are significant benefits to simultaneous surveys in that they allow dialogue between the CMS and the Joint Commission that leads to enhanced understanding of how each entity conducts its evaluation process. This approach can also reduce confusion regarding sometimes seemingly different findings from two oversight bodies and can optimize opportunities for leveraging change in laboratories.

Qualifications and Supply of Laboratory Personnel

Finally, while the GAO's lengthy and detailed review addresses many issues associated with laboratory quality, it does not address a long-acknowledged shortcoming of CLIA requirements—the qualifications of laboratory personnel. The Joint Commission believes that the personnel standards currently required by CLIA are insufficient to adequately protect patients and the public health. For example, CLIA requires only an Associate Degree and minimal laboratory training to perform tests of high complexity, and lacks personnel requirements for waived tests which account for 81 percent of the testing that takes place in the nation's laboratories. Today, the problems underlying failures in laboratory performance most commonly cited by experts in the field are the growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory tests in hospitals. By not addressing this serious shortcoming in the scope of its review, GAO has missed an important opportunity to leverage potential improvements in laboratory performance and protect the public interest.

Concluding Remarks

In conclusion, the long-standing, positive working relationship among CMS, the Joint Commission, and its colleague accrediting bodies has benefited the public through assuring continuous access to and application of state-of-the-art methods for evaluating quality and safety in laboratories. These efforts to continuously improve health care quality and patient safety not only serve to protect the interests of patients and the public, but they also ensure that the Medicare program and other payers are making sound purchasing decisions. The Joint Commission's leadership role in this area is evidenced by the fact that many private insurers and employers, including employee health plans, require that hospitals and laboratories serving their plan members be accredited by the Joint Commission.

The Joint Commission thanks the Subcommittee for its ongoing interest in the quality and safety of services provided in our nation's clinical laboratories. We are firmly committed to working with all of our partners—public and private—to ensure continuous improvement in these services.